PTO/SB/08A (06-03)

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Substitute to Agrm 1449A/P Complete if Known **Application Number** 10/646,391 INFORMATION DISCLOSURE Filing Date 8/21/2003 First Named Inventor Gleave et al. STATEMENT BY APPLICANT Art Unit 1614 (use as many sheets as necessary) **Examiner Name** of 3 Attorney Docket Number Sheet 1 **UBC.P-035** 

	U.S. PATENT DOCUMENTS								
Examiner	Cite	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant				
Initials*	No. <sup>1</sup>	Number-Kind Code <sup>2 (il known)</sup>	IVIIVI-DD-1111	Applicant of Offed Document	Figures Appear				
		US- <del>US</del> 6,172,216 B1	1/9/2001	Bennett et al.					
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Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures	T <sup>®</sup>
		WO 00/49937 WO 02/22635 A1 WO 03/062421 A1 WO 03/072591 A1	8/31/2000 3/21/2002 7/31/2003 9/4/2003	The University of British Columbia ISIS Pharmaceuticals, Inc. The University of British Columbia The University of British Columbia	Appear	
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Examiner Signature	<del>-</del>	Date Conside	red

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Complete if Known **Application Number** 10/646,391 **INFORMATION DISCLOSURE** Filing Date 8/21/2003 First Named Inventor STATEMENT BY APPLICANT Gleave et al. Art Unit 1614 **Examiner Name** (use as many sheets as necessary) Attorney Docket Number Sheet 3 of UBC.P-035

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		GLEAVE ET AL., Targeting anti-apoptotic genes upregulated by androgen withdrawal using antisense oligonucleotides to enhance androgen- and chemo-sensitivity in prostate cancer, Investigational New Drugs, 2002, Page(s) 145-158, Volume 20	
		GLEAVE ET AL., Use of Antisense Oligonucleotides Targeting the Antiapoptotic Gene, Clusterin/Testosterone-Repressed Prostate Message 2, To Enhance Androgen Sensitivity and Chemosensitivity in Prostate Cancer, Urology, 2001, Page(s) 39-49, Volume 58, XP-002262320	
		GLEAVE ET AL., Antisense therapy: Current status in prostate cancer and other malignancies, Cancer and Metastasis Reviews, 2002, Page(s) 79-92, Volume 21	
		GLEAVE ET AL., Antisense Targets to Enhance Hormone and Cytotoxic Therapies in Advanced Prostate Cancer, Current Drug Targets, 2003, Page(s) 209-221, Volume 4, XP-009021409	
		JONES ET AL., Molecules in focus: Clusterin, The International Journal of Biochemistry & Cell Biology, 2002, Page(s) 427-431, Volume 34	
		MIYAKE ET AL., Antisense TRPM-2 Oligodeoxynucleotides Chemosensitize Human Androgen-independent PC-3 Prostate Cancer Cells Both in Vitro and in Vivo, Clinical Cancer Research, 2000, Page(s) 1655-1663, Volume 6, XP-000960694	
		MIYAKE ET AL., Testosterone-repressed Prostate Message-2 Is an Antiapoptotic Gene Involved in Progression to Androgen Independence in Prostate Cancer, Cancer Research, 2000, Page(s) 170-176, Volume 60, XP-002907064	
		MIYAKE ET AL., Synergistic Chemsensitization and Inhibition of Tumor Growth and Metastasis by the Antisense Oligodeoxynucleotide Targeting Clusterin Gene in a Human Bladder Cancer Model, Clinical Cancer Research, 2001, Page(s) 4245-4252, Volume 7, XP-002263075	
		MIYAKE ET AL., Novel therapeutic strategy for advanced prostate cancer using antisense oligodeoxynucleotides targeting antiapoptotic genes upregulated after androgen withdrawal to delay androgen-independent progression and enhance chemosensitivity, International Journal of Urology, 2001, Page(s) 337-349, Volume 8, XP-002262321	
		SENSIBAR ET AL., Prevention of Cell Death Induced by Tumor Necrosis Factor a in LNCaP Cells by Overexpression of Sulfated Glycoprotein-2 (Clusterin), Cancer Research, 1995, Page(s) 2431-2437, Volume 55, XP-002930082	
		ROSENBERG ET AL., Clusterin: Physiologic and Pathophysiologic Considerations, Int. J. Biochem. Cell Biol., 1995, Page(s) 633-645, Volume 27, No. 7, XP-001002844	

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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				First Named Inventor	Gleave et al.		
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	_			Examiner Name			
Sheet	3	of	3	Attorney Docket Number	UBC.P-035		

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		WILSON ET AL., Clusterin is a secreted mammalian chaperone, TIBS, 2000, Pages 95-97, Volume 25	
	····	WONG ET AL., Molecular characterization of human TRPM-2/clusterin, a gene associated with sperm maturation, apoptosis and neurodegeneration, Eur. J. Biochem, 1994, Pages 917-925, Volume 91, XP-001146404	
		ZANGEMEISTER-WITTKE ET AL., A Novel Bispecific Antisense Oligonucleotide Inhibiting Both bcl-2 and bcl-xL Expression Efficiently Induces Apoptosis in Tumor Cells, Clinical Cancer Research, 2000, Pages 2547-2555, Volumbe 6, XP-002241562	
		ZELLWEGER ET AL., Antitumor Activity of Antisense Clusterin Oligonucleotides is Improved in Vitro and in Vivo by Incorporation of 2'O'(2-Methoxy)Ethyl Chemistry, The Journal of Pharmacology and Experimental Therapeutics, 2001, Pages 934-940, Volume 298, No. 3, XP-002262318	
		ZELLWEGER ET AL., Chemosensitization of Human Renal Cell Cancer Using Antisense Oligonucleotides Targeting the Antiapoptotic Gene Clusterin, Neoplasia, 2001, Pages 360-367, XP-009004604	
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